

Application No.: 10/562,377
Attorney Docket No.: 47675-163
First Applicant's Name: Cathy Lofton-Day
Application Filing Date: 25 August 2006
Office Action Dated: 08 December 2008
Date of Response: 08 June 2009
Examiner: Katherine D. Salmon

REMARKS

Claims 1-25 are pending and subject to restriction by the Examiner.

Claims 11, 15, 17, 19-22, and 25 have been canceled herein without prejudice, as being drawn to non-elected subject matter.

Claims 1, 4, 6, 12-14, 16, 18, 23, and 24 have herein been amended herein to be consistent with the present restriction elections.

Claim 12-14, 16, 18, 23, and 24 have been amended herein to be serially dependent upon claim 1.

No new matter has been added.

Initial required election

The Examiner, by way of restrictions, is requesting an initial election of one Group of claims from among Groups I-II:

Group I (claims 1-10, 18, 23-24) drawn to a method to distinguish between methylated and non-methylated DNA.

Group II (claims 11-17, 19-22, and 25) drawn to nucleic acids, oligomers, an array, and a kit.

Applicants herein elect **Group I** (claims 1-10, 18, 23-24). Additionally 12-14, 16, 18, 23, and 24 have been amended herein to be serially dependent upon claim 1 and should be included in this group as amended.

Further required election

Where Group I is elected, the Examiner is further requiring:

a-election of a specific target sequence or specific combination of target sequences from the group consisting of SEQ ID No. 1-39; and

b-election of a specific combination of at least two primers from the group consisting of SEQ ID No. 40-195.

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Applicants, with respect to a, herein elect SEQ ID NO:6, *with traverse*.

Applicants, with respect to b, herein elect SEQ ID NOS:50 and 128, *with traverse*.

The basis of Applicants traversal is four-fold:

First, with respect to further restriction a above, as disclosed in the specification, for example, at page 18, line 8, through page 19, line 7, in particular aspects, the genomic DNA sample is treated in such a manner that cytosine bases which are unmethylated at the 5'-position are converted to uracil, thymine, or another base which is dissimilar to cytosine in terms of hybridization behavior. It is preferred that this treatment is carried out with bisulfite (hydrogen sulfite, disulfite) and subsequent alkaline hydrolysis. Such a treatment results in the conversion of SEQ ID NO:6 to SEQ ID NOS:50 (sense) and 51 (antisense), wherein said CpG dinucleotides are methylated, or to SEQ ID NOS:128 (sense) and SEQ ID NO:129 (antisense), wherein said CpG dinucleotides are unmethylated. Therefore, SEQ ID NOS:50, 51, 128 and 129 should be grouped and examined together with SEQ ID NO:6 because they correspond to bisulfite-treated sequences for the identical sequence region of genomic SEQ ID NO:6. Specifically, as summarized in TABLE A below, SEQ ID NOS:50 and 128 are chemically treated sequences of the sense strand of SEQ ID NO:6 and SEQ ID NOS:51 and 129 are chemically treated sequences of the *complementary* antisense strand of SEQ ID NO:6 (that is, of the identical sequence region of genomic DNA), and the patentability of claims limited by these SEQ ID NOS will be determined based, *inter alia*, on the novelty of analysis based on this genomic sequence region for the claimed indications.

In summary, SEQ ID NOS:6, 50, 51, 128, and 129 should be grouped and examined together. Applicants point out that it has been the consistent practice of the Office to group the bisulfite-treated sequences with the underlying genomic sequence in a single group.

Table A: Genomic and Bisulfite-treated Sequences

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GENOMIC SEQUENCES	Upmethylated Bisulphite Sequence	Downmethylated Bisulphite Sequence
SEQ ID NO 6	SEQ ID NO 50 (sense)	SEQ ID NO 128 (sense)
	SEQ ID NO 51 (antisense)	SEQ ID NO 129 (antisense)
SEQ ID NO 21	SEQ ID NO 80 (sense)	SEQ ID NO 158 (sense)
	SEQ ID NO 81 (antisense)	SEQ ID NO 159 (antisense)

Second, with respect to further restriction a above, Applicants, respectfully appealing to Office discretion, request that SEQ ID NOS:21, 80, 81, 158, and 159 be examined together with the above summarized SEQ ID NOS:6, 50, 51, 128, and 129. As summarized in TABLE A above, SEQ ID NOS:80 and 158 are chemically treated sequences of the sense strand of SEQ ID NO:21 and SEQ ID NOS:81 and 159 are chemically treated sequences of the *complementary* antisense strand of SEQ ID NO:21 (that is, of the identical sequence region of genomic DNA), and the patentability of claims limited by these SEQ ID NOS will be determined based, *inter alia*, on the novelty of analysis based on this genomic sequence region for the claimed indications.

In summary, SEQ ID NOS:21, 80, 81, 158, and 159 should be grouped and examined together. Applicants point out that it has been the consistent practice of the Office to group the bisulfite-treated sequences with the underlying genomic sequence in a single group.

In conclusion, with respect to further restriction a above, for this further election, Applicants request that SEQ ID NOS:6, 50, 51, 128, and 129, and SEQ ID NOS:21, 80, 81, 158, and 159 be grouped and examined together.

Alternatively, for this further election, at a minimum Applicants request that SEQ ID NOS:6, 50, 51, 128, and 129 should be grouped and examined together.

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Applicants point out that it has been the consistent practice of the Office to group the bisulfite-treated sequences with the underlying genomic sequence in a single group.

Third, with respect to further restriction b above, Applicants point out that SEQ ID NOS:40-195 are not primers as suggested by the Examiner, but rather, as discussed in detail above, correspond to the chemically converted nucleic acids of genomic SEQ ID NOS:1-39. Therefore, Applicants traverse this restriction as asserted by the Examiner and respectfully request the grouping and examination of sequences as requested above.

Fourth, with respect to further restriction b above, if the Examiner deems that a restriction to specific primers is required, Applicants request that general primers SEQ ID NOS:196-225 be grouped for examination. These primers are summarized in the Specification at Table 3 (page 38), and at pages 40, line 14, to page 41, line 26.

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CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request entry of the present Response and Amendment and allowance of the amended claim set provided herein. The Examiner is encouraged to phone Applicants' attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

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Respectfully submitted,
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